

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA**

WILLIAM D. MCCLUSKEY, as Surviving)
Spouse and as Personal Representative of)
the Estate of MARY L. MCCLUSKEY,)
deceased,)

PLAINTIFF,)

v.)

MERCK & CO., INC., a foreign)
Corporation; PFIZER INC., a)
Delaware Corporation; PHARMACIA)
CORPORATION, a Delaware)
Corporation; MONSANTO COMPANY,)
a Delaware Corporation;)

G.D. SEARLE, LLC, a Delaware)
Corporation;)

JAMES A. STEWART, an Individual;)
ANNA LEIGH WEBB, an Individual;)
CEDRIC D. ANDERSON, an Individual;)
TRAVIS TAYLOR, an Individual;)
ROBERT VANDELUNE, an Individual;)
and fictitious Defendants A, B, C & D,)
being those persons, firms or Corporations)
whose fraud, scheme to defraud,)
and/or other wrongful conduct caused or)
contributed to the Plaintiff's injuries and)
damages, and whose true names and)
identities are presently unknown to)
Plaintiff, but will be substituted by)
amendment when ascertained,)

DEFENDANTS.)

CIVIL ACTION NUMBER:

**ANSWER AND DEFENSES OF ANSWERING DEFENDANTS TO
PLAINTIFF'S COMPLAINT**

Defendants Pfizer Inc. (“Pfizer”), Pharmacia Corporation (“Pharmacia” and improperly captioned in Plaintiff’s Complaint as Monsanto Company), G. D. Searle LLC (“Searle” and also improperly captioned in Plaintiff’s Complaint as G.D. Searle, LLC “), Travis Taylor (“Taylor”), and Robert Vandelune (“Vandelune”), (collectively the “Answering Defendants”), hereby answer Plaintiff’s Complaint in this action and state as follows:

PRELIMINARY STATEMENT

Celebrex® is a prescription medication developed by Searle. On December 31, 1998, Celebrex® was approved as labeled by the United States Food and Drug Administration. At that time, Celebrex® was manufactured, marketed and distributed in the United States by Searle to be prescribed by healthcare providers authorized by law to prescribe medications in accordance with their approval by the FDA. Prior to April 2003, Pfizer co-promoted Celebrex® in the United States. In April of 2003, Pfizer merged with Pharmacia, and the responsibilities for Celebrex® were reallocated. Searle is presently a wholly-owned third tier subsidiary of Pharmacia, which in turn is a wholly-owned subsidiary of Pfizer.

To the extent any allegations in Plaintiff’s Complaint refer to Vioxx® and/or Merck & Co., Inc. (“Merck”), such allegations are not directed to

Answering Defendants and no answer is required of Answering Defendants. To the extent an answer is deemed required, Answering Defendants lack sufficient information or knowledge to form a belief as to the truth of the allegations and therefore deny the same.

This preliminary statement is incorporated by reference in its entirety in response to each and every paragraph of Plaintiff's Complaint.

**ANSWERING:
PARTIES, JURISDICTION AND VENUE**

1. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained in this Paragraph, and therefore deny same. Answering Defendants admit that, during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as specifically admitted herein, Answering Defendants deny the allegations in this Paragraph as they relate to Answering Defendants.

2. The allegations in this Paragraph are not directed towards Answering Defendants, and therefore, no answer is required.

3. Answering Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York and is registered to do business in Alabama. Answering Defendants state that

Plaintiff's allegation regarding place of service is a legal conclusion to which no response is required. Answering Defendants admit that, during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as specifically admitted herein, Answering Defendants deny the allegations in this Paragraph as they relate to Answering Defendants.

4. Answering Defendants admit that Pharmacia is a corporation existing under the laws of the State of Delaware with its principal place of business in the State of New Jersey and is registered to do business in Alabama. Answering Defendants state that Plaintiff's allegation regarding place of service is a legal conclusion to which no response is required. Answering Defendants admit that, during certain period(s) of time, Pharmacia co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as specifically admitted herein, Answering Defendants deny the allegations in this Paragraph as they relate to Answering Defendants.

5. Answering Defendants state that Plaintiff's allegation regarding place of service is a legal conclusion to which no response is required.

Answering Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc., and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has never designed, produced, manufactured, sold, resold, or distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has never manufactured, marketed, sold or distributed Celebrex®, the Answering Defendants are, therefore, stating that the 2000 Monsanto is not a proper party in this matter. Except as admitted herein, Answering Defendants deny the allegations in this Paragraph as they relate to Answering Defendants.

6. Answering Defendants admit that Searle is a wholly-owned subsidiary of Pharmacia Corporation, which is in turn a wholly-owned subsidiary of Pfizer. Searle is a Delaware limited liability company with its principal place of business in Illinois and is registered to do business in

Alabama. Answering Defendants state that Plaintiff's allegation regarding place of service is a legal conclusion to which no response is required. Answering Defendants admit that, during certain period(s) of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with the approval by the FDA. Except as admitted herein, Answering Defendants deny the allegations in this Paragraph as they relate to Answering Defendants.

7. Answering Defendants admit that Travis Taylor and Robert Vandellune are sales representatives for Pfizer. Answering Defendants state that Plaintiff's allegation regarding place of service is a legal conclusion to which no response is required. Except as admitted herein, Answering Defendants deny the allegations in this Paragraph as they relate to Answering Defendants.

8. The allegations in this Paragraph are not directed towards Answering Defendants, and therefore, no answer is required.

9. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

10. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

**ANSWERING:
FACTUAL BACKGROUND
Properties of COX Inhibitors**

11. Answering Defendants state that Celebrex® is a selective COX-2 inhibitor and is a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs (“NSAIDs”). Answering Defendants state that, during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. The remaining allegations in paragraph 11 are not directed at Answering Defendants and, therefore, no response is required. Except as admitted herein, Defendants deny the allegations in this Paragraph as they relate to Answering Defendants.

12. The allegations contained in Paragraph 12 are not directed towards Answering Defendants and, therefore, no response is required.

13. The allegations in Paragraph 13 are not directed towards Answering Defendants and, therefore, no response is required. To the extent a response is deemed required, Answering Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of

Celebrex is believed to be due to inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme.” Plaintiff fails to provide the proper context for the remaining allegations in Paragraph 13 and Answering Defendants, therefore, lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in Paragraph 13.

14. The allegations in Paragraph 14 are not directed towards Answering Defendants and, therefore, no response is required. To the extent a response is deemed required, Answering Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme.” Plaintiff fails to provide the proper context for the remaining allegations in Paragraph 14 and Answering Defendants, therefore, lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in Paragraph 14.

15. The allegations in Paragraph 15 are not directed towards Answering Defendants and, therefore, no response is required. To the extent

a response is deemed required, Answering Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme.” Plaintiff fails to provide the proper context for the remaining allegations in Paragraph 15 and Answering Defendants, therefore, lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in Paragraph 15.

16. The allegations in Paragraph 16 are not directed towards Answering Defendants and, therefore, no response is required. To the extent a response is deemed required, Answering Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme.” Plaintiff fails to provide the proper context for the remaining allegations in Paragraph 16 and Answering Defendants, therefore, lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in Paragraph 16.

17. The allegations in Paragraph 17 are not directed towards Answering Defendants and, therefore, no response is required. To the extent a response is deemed required, Answering Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme.” Plaintiff fails to provide the proper context for the remaining allegations in Paragraph 17 and Answering Defendants, therefore, lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in Paragraph 17.

18. The allegations in Paragraph 18 are not directed towards Answering Defendants and, therefore, no response is required. To the extent a response is deemed required, Answering Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme.” Plaintiff fails to provide the proper context for the remaining allegations in Paragraph 18 and Answering Defendants, therefore, lack sufficient information or knowledge to form a

belief as to the truth of the allegations and, therefore, deny the remaining allegations in Paragraph 18.

19. The allegations in Paragraph 19 are not directed towards Answering Defendants and, therefore, no response is required. To the extent a response is deemed required, Answering Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme.” Plaintiff fails to provide the proper context for the remaining allegations in Paragraph 19 and Answering Defendants, therefore, lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in Paragraph 19.

20. The allegations in Paragraph 20 are not directed towards Answering Defendants and, therefore, no response is required. To the extent a response is deemed required, Answering Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme.” Plaintiff fails to provide the proper

context for the remaining allegations in Paragraph 20 and Answering Defendants, therefore, lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in Paragraph 20.

21. The allegations in Paragraph 21 are not directed towards Answering Defendants and, therefore, no response is required. To the extent a response is deemed required, Answering Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) enzyme.” Plaintiff fails to provide the proper context for the remaining allegations in Paragraph 21 and Answering Defendants, therefore, lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in Paragraph 21.

ANSWERING:
The VIOXX® Timeline

22. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

23. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

24. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

25. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

26. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

27. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

28. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

29. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

30. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

31. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

32. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

33. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

34. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

35. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

36. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

37. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

38. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

39. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

40. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

41. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

42. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

43. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

44. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

45. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

46. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

47. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

48. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

49. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

50. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

51. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

52. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

53. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

54. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

55. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

56. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

57. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

58. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

59. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

60. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

61. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

62. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

63. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required. To the extent a response is deemed required, Answering Defendants admit that Vioxx® was withdrawn from the United States market on September 30, 2004.

64. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

65. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

66. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

67. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

68. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required.

**ANSWERING:
The Celebrex® Timeline**

69. This Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants state that Celebrex® is a prescription medication developed by Searle. Searle submitted a New Drug Application for Celebrex® on June 29, 1998, which was approved as labeled by the United States Food and Drug Administration on December 31, 1998. At that time, Celebrex® was manufactured, marketed and distributed in the United States by Searle to be

prescribed by healthcare providers authorized by law to prescribe medications in accordance with their approval by the FDA. Prior to April 2003, Pfizer co-promoted Celebrex® in the United States. In April of 2003, Pfizer merged with Pharmacia, and the responsibilities for Celebrex® were reallocated. Searle is presently a wholly-owned third tier subsidiary of Pharmacia, which in turn is a wholly-owned subsidiary of Pfizer. Answering Defendants state that during certain period(s) of time, Searle and Pfizer co-promoted and marketed Celebrex®. Except as specifically admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

70. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

71. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

72. Answering Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

73. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants. Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information.

74. Answering Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which were at all times adequate and comported with applicable standards of care and law. Answering Defendants further state that the referenced human and animal studies speak for themselves and deny any characterization of them. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

75. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants. Answering Defendants further state that the referenced FDA safety review speaks for itself and deny any characterization of it.

76. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

77. This Paragraph contains allegations relating to Vioxx which are not directed towards Answering Defendants, and therefore, no response is required. To the extent a response is deemed required, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore, deny the same.

78. This Paragraph contains allegations relating to Vioxx which are not directed towards Answering Defendants, and therefore, no response is required. To the extent a response is deemed required, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore, deny the same.

79. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required. To the extent a response is deemed required, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore, deny the same.

80. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants. Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-

approved prescribing information. The potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which were at all times adequate and comported with applicable standards of care and law. Answering Defendants state that the referenced studies speak for themselves and deny any characterization at them.

81. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

82. Answering Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which were at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

83. This Paragraph contains allegations relating to Vioxx which are not directed towards Answering Defendants, and therefore, no response is required.

84. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required. To the extent a response is deemed required, Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein, and therefore, deny the same.

85. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations as directed towards Answering Defendants contained in this Paragraph, and therefore, deny the same.

86. Answering Defendants deny the allegations contained in this Paragraph.

87. Answering Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which were at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

88. Answering Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which were at all times adequate and comported with applicable standards of care and law. Defendants state that the referenced studies speak for themselves and deny any characterization at them. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

89. This Paragraph contains allegations relating to Vioxx® which are not directed towards Answering Defendants, and therefore, no response is required. To the extent a response is deemed required, Answering Defendants admit that Vioxx® was withdrawn from the United States market on September 30, 2004.

90. With regard to the allegations contained in this Paragraph of the Complaint, Answering Defendants admit that the FDA sent a letter to Pfizer dated January 10, 2005. Answering Defendants state that this letter speaks for itself and deny any characterization of it. Except as admitted herein,

Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

91. With regard to the allegations contained in this Paragraph of the Complaint, Answering Defendants state that the referenced studies speak for themselves and deny any characterization at them.

92. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

93. Answering Defendants state that Celebrex® and Bextra® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® and Bextra® were and are adequately described in their FDA-approved prescribing information, which were at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
Fraudulent Concealment, Tolling and Estoppel

94. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

95. Answering Defendants state they are without knowledge or information sufficient to form a belief as to the allegation with regard to the

Decedent, and therefore, deny the same. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

96. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein regarding Decedent and therefore deny the same. Answering Defendants state that this Paragraph also contains legal conclusions to which no response is required. Answering Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which were at all times adequate and comported with applicable standards of care and law. To the extent a response is deemed required, Answering Defendants admit that they have such duties as are imposed by applicable law but deny the allegations contained in this Paragraph as they relate to Answering Defendants. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

97. Answering Defendants have insufficient information or knowledge to form a belief as to the truth of the allegations contained therein regarding Plaintiff William McCluskey, and therefore deny the same.

98. Answering Defendants state that the potential affects of Celebrex® was and is adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

**ANSWERING:
CAUSES OF ACTION
COUNT I – STRICT LIABILITY AND/OR NEGLIGENCE PER SE
(Against Merck and Pfizer)
Restatement of Torts (Second) § 402A
or
Restatement of Torts (Third): Prod. Liab. § 6**

99. Answering Defendants incorporate their responses to Paragraphs 1-98 as if set forth fully herein.

100. Answering Defendants admit that, during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Answering Defendants also state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants deny that Celebrex® was defective or unreasonably dangerous. Except as admitted

herein, Answering Defendants deny the allegations in this Paragraph as they relate to Answering Defendants.

101. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is required, Answering Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations concerning whether Celebrex® reached prescribing physicians, consumers, and/or decedent, and if so, in what condition, and therefore, deny the same.

102. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Except as admitted herein, Answering Defendants deny the allegations in this Paragraph, including all of its subparts, as they relate to Answering Defendants. Answering Defendants deny that Celebrex® was defective or unreasonably dangerous.

In response to the unnumbered paragraph after Paragraph 102, Answering Defendants deny that Celebrex® caused Plaintiff and/or decedent any harm and deny that Plaintiff is entitled to any damages.

Except as admitted herein, Answering Defendants deny the allegations in this Paragraph as they relate to Answering Defendants.

**ANSWERING:
COUNT II – NEGLIGENCE
(Against Merck and Pfizer)**

103. Answering Defendants incorporate their responses to Paragraphs 1-102 as if set forth fully herein.

104. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants admit that they have such duties as are imposed by applicable law. Except as stated herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

105. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Answering Defendants also state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering

Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

106. Answering Defendants admit that, during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

107. Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information.

108. Answering Defendants deny the allegations contained in this Paragraph, including all of its subparts, as they relate to Answering Defendants.

109. Answering Defendants state that, during certain period(s) of time, Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States for the indications set forth in the FDA-approved package

inserts and as permitted by law. Answering Defendants also state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Further, Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

110. Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Except as stated herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

111. Answering Defendants deny that Celebrex® caused Plaintiff and/or decedent any harm and deny that Plaintiff is entitled to any damages. Answering Defendants deny the remaining allegations contained in this Paragraph as they relate to Answering Defendants.

ANSWERING:
COUNT III – FAILURE TO WARN
(Against Merck and Pfizer)
Restatement Torts (Second) § 388
or
Restatement of Torts (Third): Prod. Liab. §6

112. Answering Defendants incorporate their response to Paragraphs 1-111 as if set forth fully herein.

113. Answering Defendants admit that they have such duties as are imposed by applicable law, but deny that they breached any such duty. Except as stated herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

114. Answering Defendants state that Celebrex® was and is safe and effective when used in accordance with their FDA-approved prescribing information. Further, Answering Defendants state that the potential effects of Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Answering Defendants deny that Celebrex® was defective or unreasonably dangerous. Except as admitted herein, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.

115. Answering Defendants state that this Paragraph contains legal conclusions to which no response is required. To the extent a response is deemed required, Answering Defendants deny the allegations contained in this Paragraph as they relate to Answering Defendants.